US Army Medical Research and Materiel

Technology Available for Licensing

Sustained Release Non-Steroidal, Anti-Inflammatory and Lidocaine PLGA Microspheres

This invention provides compositions for release of non-steroidal anti-inflammatory drugs (NSAIDs) and lidocaine from biocompatible, biodegradable poly (DL-lactide-co-glycolide) (PLGA) microspheres. The product could be applied into soft tissues surrounding a surgical incision or traumatic wound site where it sustains local release of the NSAID. It is available as a hydrophobic end-capped polymer with terminal residues as esters and as a hydrophilic uncapped polymer with the terminal residues as carboxylic acids.

NSAIDs have been effective in reducing inflammation and inducing analgesia. They are used to treat a variety of conditions, including arthritis, dental pain due to decay or trauma, and pain following injuries or surgery. However, the conventional oral dosage forms of these drugs characteristically have short half-lives. Although slow release oral dosage forms are available they result in inefficient and systemic delivery of the drug. Large doses administered by conventional dosing regimens can result in toxicity. Since surgical and traumatic wounds can take weeks to heal, it would be beneficial for local delivery of NSAIDs to last for durations longer than 24 hours and up to 2 months from a single dose. Also, acute dental pain is a significant cause (21% of sick calls) of lost duty time for military personnel, which impacts combat readiness. A need exists for a NSAID that provides a sustained of the drug directly into the affected soft tissue.

The invention provides for fast, localized and sustained release of NSAIDs, in contrast to currently available NSAIDs. Chronic use of oral NSAIDs can cause testinal bleeding, resulting in ulcers in 25 % of ne invention eliminates this and other drawbacks.

Features and advantages:

- **Achieves high encapsulation efficiency and 'burst-free' release without an additive or filler**
- **May be released for durations ranging from 24 hours to 2 months**
- **Can encapsulate ketoprofen, ibuprofen, flurbiprofen, aspirin, or acetominophen**
- **May be combined with a localized anesthetic, such as lidocaine, xylocaine, or etiod**

Patent Status

Patent Application No.: 6,528,097
Available from: www.uspto.gov
Issued: March 4, 2003
Docket No.: WRAIR 97-03A

Point of Contact

Dr. Paul C. Mele
Director, Office of Research and Technology Applications
USAMRMC, MCMR-ZA-J
504 Scott St., Ft. Detrick, MD 21702-5012
E-mail: paul.mele@amedd.army.mil
Voice: 301-619-6664/2032/7219 Fax: 301-619-5034

KEYWORDS: PLGA microspheres; NSAID; lidocaine; prolonged release

Licensing Opportunities • Patent licenses are available to companies with commercial interests